STATE OF MICHIGAN

DEPARTMENT OF LABOR & ECONOMIC GROWTH

OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX
Petitioner **File No. 89099-001**

v

Connecticut General Life Insurance Company
Respondent
_____/

Issued and entered
this _____ day of June 2008
by Ken Ross
Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On April 10, 2008, XXXXX, on behalf of her minor daughter XXXXX (Petitioner), filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The Commissioner reviewed the request and accepted it on April 17, 2008.

This case required an analysis by a health care professional so the Commissioner assigned it to an independent review organization (IRO), which submitted its recommendation on April 30, 2008.

II
FACTUAL BACKGROUND

The Petitioner has health care coverage as an eligible dependent under a group plan with CIGNA HealthCare that is underwritten by Connecticut General Life Insurance Company (Connecticut General).

The Petitioner has been diagnosed with Legg-Calvé-Perthes disease (LCPD), a degenerative disease of the hip joint, where a loss of bone mass may lead to some degree of collapse of the hip joint and deformity of the ball of the femur and the surface of the hip socket. The disease, typically found in young children, can lead to osteoarthritis in adults.

Because of the LCPD, the Petitioner was prescribed botulinum toxin (type A) injections in her right hip adductor muscles for spasms and tightness. On May 10, 2007, 200 units of botulinum toxin were injected in two locations. When the claim for the injection was submitted, Connecticut General denied coverage, saying it was an experimental, investigational, or unproven service.

The Petitioner appealed but Connecticut General maintained its denial. The Petitioner exhausted Connecticut General's internal grievance process and received its final adverse determination letter dated March 5, 2008.

III
ISSUE

Was Connecticut General correct in denying coverage for the Petitioner's botulinum toxin injection?

IV
ANALYSIS

Petitioner's Argument

The Petitioner says that her physicians, Dr. XXXXX (pediatric orthopaedic surgeon) and Dr. XXXXX (physical medicine and rehabilitation), recommended the injections for hip adductor spasticities resulting from the LCPD. In a letter dated February 6, 2008, Dr. XXXXX said in part:

> Due to her diagnosis, [the Petitioner] has spasm and tightness of her hip adductor muscle. This tightness and spasm interferes with her ability to move her hip and to participate in her rehabilitation program and recovery. Botulinum toxin injections help the muscle to relax. This relaxation allows the hip to rest in a more abducted position, which promotes healing. It allows for better participating in therapy. These injections are medically necessary.

The Petitioner believes Connecticut General should cover the claim because the injection was medically necessary and it has provided coverage in the past.

Connecticut General Life Insurance Company's Argument

Connecticut General asserts that its denial for coverage of the Petitioner's injection was correct because the Petitioner's certificate of insurance (the certificate) excludes coverage for treatments which are considered experimental, investigational or unproven. The certificate says:

> **Exclusions, Expenses Not covered and General Limitations**
>
> * * * Payment for the following is specifically excluded from this plan:
>
> * * *
>
> - for or in connection with experimental, investigational or unproven services;
>
> Experimental, investigational and unproven services are medical, surgical, diagnostic, psychiatric, substance abuse or other health care technologies, supplies, treatments, procedures, drug therapies or devices that are determined by the utilization review Physician to be:
>
> - not demonstrated, through existing peer-reviewed, evidence-based, scientific literature to be safe and effective for treating or diagnosing the condition or sickness for which its use is proposed;
>
> - not approved by the U.S. Food and Drug Administration (FDA) or other appropriate regulatory agency to be lawfully marketed for the proposed use;
>
> - the subject of review or approval by an Institutional Review Board for the proposed use except as provided in the "Clinical Trials" section of the plan; or
>
> - the subject of an ongoing phase I, II or III clinical trial, except as provided in the "Clinical Trials" section of this plan.

Connecticut General's medical policy ("CIGNA HealthCare Coverage Position") on botulinum toxin says that it is covered as medically necessary for dystonias and spasticities. However, the policy does not specifically mention LCPD and in its final adverse determination Connecticut General said that "a focal dystonia or other spastic condition has not been established from the information received." Moreover, the medical policy says that the provisions of the

certificate supersede the information in the medical policy.

Connecticut General argues that botulinum toxin injections for the treatment of LCPD is considered experimental, investigational, or unproven, and is therefore excluded as a benefit under the terms of the certificate.

Commissioner's Review

To help the Commissioner resolve the issue of whether botulinum toxin injections for the treatment of the Petitioner's condition were appropriate, the matter was assigned to an IRO for the recommendation of an expert. The IRO reviewer is a practicing physician who is certified by the American Board of Physical Medicine and Rehabilitation and the American Board of Independent Medical Examiners and is published in peer-reviewed medical literature. The IRO reviewer concluded: "[I]t is the determination of this reviewer that the Botox injection for date of service May 10, 2007, is considered experimental/investigational for [the Petitioner's] condition."

The IRO report said:

> Botulinum toxin injections for Legg-Calvé-Perthes syndrome are experimental/investigational. Legg-Calvé-Perthes syndrome is an idiopathic avascular osteonecrosis of the capital femoral epiphysis of the femoral head, caused by compromise of the blood supply to the femoral head. The goal of treatment is to avoid severe degenerative arthritis by avoiding wear and tear on the joint. Braces and physiotherapy (including an emphasis on swimming and other reduced /non weight-bearing exercise) are frequent components of the treatment plan. Analgesics are often required. In the long-term, orthopedic surgical interventions may be necessary.
>
> There is no established role of botulinum toxin injections in the management of Legg-Calvé-Perthes syndrome. A Medline search of Legg-Calvé-Perthes + botulinum toxin revealed no published papers on this topic. Botulinum toxin injections are not Food and Drug Administration (FDA) approved for Legg-Calvé-Perthes syndrome.

The IRO reviewer also noted that at the May 10, 2007, examination the Petitioner was only using Motrin on an as needed basis, that she had full range of motion of the left hip, that the right hip was somewhat limited, and that there was no documentation of spasticity.

The Commissioner is not required in all instances to accept the IRO's recommendation.

However, the IRO recommendation is afforded deference by the Commissioner; it is based on extensive expertise and professional judgment. The Commissioner can discern no reason why that judgment should be rejected in the present case.

The Commissioner accepts the findings of the IRO reviewer and finds that botulinum toxin injections in the Petitioner's case are experimental, investigational, or unproven for the treatment of her condition.

V
ORDER

The Commissioner upholds Connecticut General's March 5, 2008, final adverse determination. Connecticut General's denial was appropriate under the terms of the certificate.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the Circuit Court for the county where the covered person resides or in the Circuit Court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of the Office of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

Ken Ross
Commissioner